AMERICAN
ASSOCIATION
OF BLOOD BANKS

October 15, 1999

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Docket No 97D-0318

Re: Guidance For Industry Revised Precautionary Measures to Reduce the Possible Risk of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products.

To Whom it May Concern:

The AABB is the professional association for approximately 2200 institutions engaged in the collection and transfusion of blood and blood products, including all American Red Cross blood services regions, independent community blood centers, hospital-based blood banks and transfusion services, and more than 8500 individuals engaged in all aspects of blood collection, processing and transfusion. Our members are responsible for virtually all of the blood collected and more than eighty percent of the blood transfused in this country. The AABB's highest priority is to maintain and enhance the safety of the nation's blood supply.

The AABB has previously submitted comments on Section D. Recommended Questions for Identifying Donors at Risk for Exposure to BSE. The following comments relate to other sections of the guidance.

1.) The AABB has not had sufficient time to analyze the impact of these specific provisions on the blood supply. For that reason, we take no position on the merits of these provisions at this time.

2.) The AABB is, however, deeply concerned about the lack of public discussion and comment on the regulatory proposals in this guidance, particularly those related to nvCJD. All public discussions at the various advisory committee meetings focused solely on the issue of donor deferral for travel to the United Kingdom. At no time has the issue of how to handle previously distributed blood products been addressed. The AABB feels strongly that FDA should not enforce the provisions in this guidance until adequate input and public discussion has occurred, and revisions made if warranted.

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Although the AABB had not taken a position on the merits of these requirements, we are relaying the following comments from our members.

a.) This new guidance should be implemented in a strictly prospective fashion for the theoretical risk factors to nvCJD associated with travel to Great Britain for more than 6 months between 1980 and 1996. When this question is implemented, a yes answer **should not be considered post donation information for previous donations, it should not require filing an error/accident report for previous donations, it should not require consignee notification for interdiction of in-date products from previous donations, and it should not require recipient notification.** Likewise, the same policy would apply should FDA retain the requirement for questioning donors about injectable bovine insulin manufactured in BSE endemic countries.

This approach is important in order to minimize the effects of this new guidance on blood banks. Since it is likely that Fresh Frozen or Recovered Plasma will have been prepared from every donor for each donation, examining records to determine whether there are any in-date products will be extremely time consuming. A new requirement, in response to a potential theoretical risk which is not even known to exist in the United States, does not need to be implemented in the same manner as a known significant disease risk where every effort must be made to avoid transfusion of any potentially suspect blood component.

b.) Section V grants discretion to the care provider in determining whether recipient tracing and medically appropriate counseling should be performed in cases of a donor found to have CJD, nvCJD, risk factors for CJD or if withdrawal is recommended in cases under investigation for nvCJD. Current practice is to treat all consignee notifications the same way, regardless of significance. Hospitals are already uncertain when these notices contain vital information and when the notice is required by FDA but does not contain information pertinent to the health of the recipient, or information upon which the recipient can take action. In many instances, hospitals feel obligated to notify the recipient, even in the absence of any information upon which the recipient can act, simply because they have received a notice from the blood collecting facility. We are concerned that notification will automatically be sent on to the recipient without any evaluation by the health care provider.

Just as care providers are given discretion in notifying recipients, blood banks should have the discretionary ability to determine when consignees should be notified. Hospitals (that is, the pathologist who receives most of these kinds of notifications) are ill equipped to determine their significance for the recipient. Of all the parties in the decision chain, the blood center physician has more scientific knowledge in these areas than any other party and should be willing and able to make a medical judgment as to whether notification does or does not serve a useful purpose. Blood banks should be permitted to discuss notification policies with their hospital customers and arrive at mutually

acceptable notification procedures. For example, if the consignee adopts a policy that recipient notification and counseling will not be done there is no reason to even notify the consignee about cases of a donor found to have CJD, nvCJD, risk factors for CJD or if withdrawal is recommended in cases under investigation for nvCJD.

Many members failed to understand the Note in Section V, and assumed that recipient notification would be required for nvCJD exposure risk factors (travel to UK and injectable bovine products from BSE endemic countries). This notification is not necessary, and that provision should not be changed, but perhaps it could be emphasized in some manner. Of course if consignee notification is not required for these exposure risk factors as discussed in item a.), then recipient notification will not be an issue.

c.) The recommendation to search records to identify prior collections from that donor back indefinitely to the extent that electronic or other readily retrievable records are available is ambiguous. Computerized records are the only records which should be considered readily retrievable. Paper and microfiche records are very time consuming to review and the information is often not stored for convenient access. This is particularly true for transfusion services. The definition of readily retrievable is only part of the problem. Even records stored on site may not have information that is readily available.

Thank you for the opportunity to submit these comments and suggestions from our members. If you have any questions, please contact Kay Gregory, Director Regulatory Affairs at 301-215-6522 or kayg@aabb.org.

Yours truly,

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